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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,137	02/06/2002	Danilo Porro	2027.547096/RFE (2005470)	8385
23720	7590	05/12/2005	EXAMINER	
WILLIAMS, MORGAN & AMERSON, P.C. 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 05/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,137

Applicant(s)

PORRO ET AL.

Examiner

Kathleen M. Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application Status

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on March 8, 2005 has been entered.
2. In response to the previous Office action, a Final rejection (mailed on November 26, 2004), Applicants filed a response (RCE) received on March 8, 2005 to enter an after final amendment filed January 28, 2005. Said amendment amended Claim 35 (the Examiner notes it is incorrectly marked "previously presented" despite the markings in the claim). Thus, Claims 35-43 are pending in the instant Office action and will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application MI97A002080 filed on September 12, 1997 and International Application No. PCT/EP98/05758 filed on September 11, 1998. The instant application is also granted the benefit of the parent application 09/508,277 filed on June 29, 2000, now USPN 6,429,006.

Information Disclosure Statement

4. The information disclosure statement filed on March 22, 2005 has been reviewed, and its references have been considered as shown by the Examiner's initials on the attached copy.

Withdrawn - Objections to the Specification

5. Previous objection to the specification for containing citations of internet addresses in an improper format is withdrawn by virtue of Applicant's amendment removing the addresses. The references are clear in the format provided.

6. Previous objection to the amendment filed March 31, 2004 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment removing said new matter. The citations are clear in the format provided.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 35-43 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's amendment to "0.881 gram lactic acid per gram glucose" which is reflective of 88.1%, listed in Table 3B.

8. Previous rejection of Claims 35-43 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for producing particular levels of lactate at particular pHs, does not reasonably provide enablement for producing 100% lactate from glucose at infinitely low pHs (see Claims 38-40) is withdrawn by virtue of Applicant's amendment requiring an initial pH of 4.5 and not requiring 100% conversion.

9. Previous rejection of Claims 35-43 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using yeast having deleted copies of their endogenous pyruvate decarboxylase or pyruvate dehydrogenase genes so as to reduce the activity of these enzymes in the yeast, does not reasonably provide enablement

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for methods using yeast having these enzymes' activities reduced by other means is withdrawn by virtue of Applicant's amendment requiring the deletion of said genes in Claim 35.

New - Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 35-43 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The initial pH of higher than 4.5. Applicant cites support in Table 7; however, Table 7 describes data wherein the initial pH was 5.4, not 4.5. The Examiner cannot find support elsewhere in the specification for an initial pH of higher than 4.5.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 38-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations of "pH of 7 or less", "pH is 4.5 or less" and "pH is 3 or less" is confusing considering the amendment to Claim 35, from which the instant claims

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depend, requiring an initial pH of higher than 4.5. Are the added limitations in Claims 39 and 40 an attempt to change the initial pH, in which the claims would be not further limiting, or do they define the final pH? Clarification is required.

Summary of Pending Issues

12. The following is a summary of issues pending in the instant application:

- a) Claims 35-43 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- b) Claims 38-40 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the limitations of “pH is 4.5 or less” and “pH is 3 or less”.

Other Art Cited

13. The Examiner cites the following to complete the record:

- a) Adachi *et al.* Modification of metabolic pathways of *Saccharomyces cerevisiae* by the expression of lactate dehydrogenase and deletion of pyruvate decarboxylase genes for the lactic acid fermentation at low pH value. *J of Fermentation and Bioengineering* (1998) 86: 284-289.

This reference is not prior art in view of the foreign priority document.

Closest Prior Art

14. Reiterated from the previous action, the following is a description of related prior art:

- a) Porro *et al.* (1995 – see IDS) teach *S. cerevisiae* GRF18 transformed with a bovine LDH gene can produce 50-70% yield lactic acid when the growth media carbon source is manipulated (see page 296, right column). However, GRF18 lacks the reduced ethanol production limitation. Porro *et al.* also teach the desire to reduce ethanol production in yeast harboring an LDH gene for the production of lactic acid. Porro *et al.* attempt this combination by transforming *S. cerevisiae* YSH 5.127-17 (a deleted *pdcl*, *pdcs*, and *pdcs* yeast strain) with a bovine LDH gene; however, the lactate production is “low” and not reported (see page 296, left column). Porro’s using YSH 5.127-17 is very similar to Applicants’ using *S. cerevisiae* CENPK113PDCΔ1,Δ5,Δ6[pLC5-KanMX] to produce a 50% lactate yield, the difference being that Applicants’ LDH gene is from *L. casei* and said gene is on an integrating vector as

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opposed to the replicative vector with bovine LDH of Porro *et al.* Thus, a case for inherency cannot be made that the teachings of Porro *et al.* would produce a 50% yield of lactate.

Conclusion

15. Claims 35-43 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action is **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

May 9, 2005